

§ 106-145.8. Records of prescription drugs.

(a) Records. – A wholesale distributor shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including all stored prescription drugs, all incoming and outgoing prescription drugs, and all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs. A wholesale distributor is not required, however, to keep a record of the lot number or expiration date of a prescription drug disposed of or distributed by the distributor.

A record of a prescription drug shall include all of the following information:

- (1) The source of the prescription drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped.
- (2) The identity and quantity of the prescription drug received and distributed or disposed of through another method.
- (3) The date the wholesale distributor received the prescription drug and the date the wholesale distributor distributed or otherwise disposed of the drug.
- (4) Documentation of the proper storage of prescription drugs. Documentation may be by manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs.

A wholesale distributor shall keep a record of a prescription drug for two years after its disposition.

(b) Inspection. – A wholesale distributor shall make inventories and records of prescription drugs available for inspection and photocopying by representatives of the Department or authorized federal, State, or local law enforcement officials. A wholesale drug distributor shall permit the Department or an authorized federal, State, or local law enforcement official to enter and inspect the distributor's premises and delivery vehicles and to audit the distributor's records and written operating procedures at reasonable times and in a reasonable manner.

A record that is kept at the inspection site or is immediately retrievable by computer or other electronic means shall be readily available for authorized inspection during the two-year retention period. A record kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, State, or local law enforcement agency. (1991, c. 699, s. 2.)